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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,168	08/02/2006	Hirotoshi Adachi	MUR-049-USA-PCT	5164

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TOWNSEND & BANTA
c/o PORTFOLIO IP
PO BOX 52050
MINNEAPOLIS, MN 55402

EXAMINER	
DICKINSON, PAUL W	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,168	ADACHI ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/6/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 6 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 2002032480 (WO '480; document already in record). WO '480 discloses an interface for a transdermal drug administration device having a flat plate comprising a plurality of two-dimensionally arranged pyramidal projections capable of piercing the skin and a plurality of through-holes (i.e. openings) capable of delivering a drug which are respectively arranged in correspondence with the projections, wherein the openings are respectively arranged in proximity to their corresponding projections (see abstract; page 14, line 30 to page 15, line 7; page 18, line 11 to page 20, line 4; figures 3 to 4). This satisfies instant claim 1. Channels for directing a drug from the openings to their corresponding projections are provided between the openings and their

corresponding projections on the flat plate (see page 18, line 11 to page 20, line 4). This satisfies instant claim 2. The ratio of openings and projections may be 1:1 (see Figure 13). This satisfies instant claims 6 and 14.

Claims 1-2, 6-7, 14, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by US 3964482 ('482). '482 discloses an interface for a transdermal drug administration device having a flat plate comprising a plurality of two-dimensionally arranged conical projections capable of piercing the skin and a plurality of openings capable of delivering a drug which are respectively arranged in correspondence with the projections, wherein the openings are respectively arranged in proximity to their corresponding projections (see abstract; page 43, lines 28-50; figures). This satisfies instant claim 1. The hollow interior of the conical projections serve as channels for directing a drug from the opening to their corresponding projection (see Figure 1). This satisfies instant claim 2. The ratio of openings and projections is 1:1 (see Figure 1). This satisfies instant claims 6 and 14. The flat plate may be made of metal or ceramics (see col 8, lines 30-59). This satisfies instant claims 7 and 18.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

> said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 and 8-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2002032480 (WO '480; document already in record). WO '480 discloses an interface for a transdermal drug administration device having a flat plate comprising a plurality of two-dimensionally arranged pyramidal projections capable of piercing the skin and a plurality of through-holes (i.e. openings) capable of delivering a drug which are respectively arranged in

correspondence with the projections, wherein the openings are respectively arranged in proximity to their corresponding projections (see abstract; page 14, line 30 to page 15, line 7; page 18, line 11 to page 20, line 4; figures 3 to 4). This satisfies instant claim 1. Channels for directing a drug from the opening to their corresponding projections are provided between the openings and their corresponding projections on the flat plate (see page 18, line 11 to page 20, line 4). This satisfies instant claim 2. The ratio of openings and projections may be 1:1 (see Figure 13). This satisfies instant claims 6 and 14-17. The dimensions of the pyramidal projections and openings are result effective parameters in providing an interface that pierces the skin and efficacious delivery of the drug (see page 11, first full paragraph; page 14, second full paragraph to page 15 first paragraph). The pyramidal projections can have a vertical height of between 1 to 1000 microns, and a projection angle, relative to the flat plate, of from about 30^{o} to about 90^{o} (see pages 12-13, bridging paragraph; page 14, third full paragraph). This information allows one to calculate the diameters possible for the base of the pyramidal projection. For illustrative purposes only, when the height is 1000 microns and the projection angle is 60^{o}, the diameter at the base of the pyramid would be about 116 microns (calculated from 116 = 2*[1000/tan 60]). WO '480 fails to disclose the pyramidal projection diameters, conical projection heights, and opening diameters disclosed in instant claims 3-5 and 8-13.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to optimize the conical projection diameters, conical

projection heights, and opening diameters to improve the lancing ability of the pyramidal projections and the percutaneous delivery of the drug. In this way, one would find the ranges given in the instant claims, through routine experimentation. WO '480 provides sufficient guidance to this end. '482 discloses projection heights of 1 to 1000 microns. This range fully encompasses Applicant's range of 100 to 700 microns. As illustrated above, the projection height and projection angles disclosed by WO '480 provide guidance to selecting appropriate base diameters, one such base diameter is 116 microns, which is encompassed by Applicant's range of 30 to 200 microns. "'[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.' In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)" MPEP § 2144.05, II.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 3964482 ('482). '482 discloses an interface for a transdermal drug administration device having a flat plate comprising a plurality of two-dimensionally arranged conical projections capable of piercing the skin and a plurality of openings capable of delivering a drug which are respectively arranged in correspondence with the projections, wherein the openings are respectively arranged in proximity to their corresponding projections (see abstract; page 43, lines 28-50; figures). This satisfies instant claim 1. The hollow interior of the conical projections serve as channels for directing a drug from the opening to their corresponding projection (see Figure 1). This satisfies instant claim 2. The

ratio of openings and projections is 1:1 (see Figure 1). This satisfies instant claims 6 and 14-17. The flat plate may be made of metal or ceramics (see col 8, lines 30-59). This satisfies instant claims 7, and 18-20. The dimensions of the openings and conical projections are result effective parameters (see col 7, line 22 to col 8, line 29). The height may be about 5 microns to about 100 microns (see col 8, lines 64-68). Guidance to selecting appropriate conical projection diameters is also given (see col 7, lines 32-58). '482 fails to disclose the conical projection diameters, conical projection heights, and opening diameters disclosed in instant claims 3-5 and 8-13.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to optimize the conical projection diameters, conical projection heights, and opening diameters to provide efficacious percutaneous delivery of the drug. In this way, one would find the ranges given in the instant claims, through routine experimentation. ‘482 provides sufficient guidance to this end. ‘482 discloses projection heights of about 5 microns to about 100 microns. This range overlaps with Applicant's range of 100 to 700 microns. The logic for this is "about 100 microns" encompasses value greater than 100 microns. Therefore, "about 5 microns to about 100 microns" overlaps with “100 to 700 microns.” “In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).” MPEP § 2144.05, I.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Primary Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

March 13, 2010